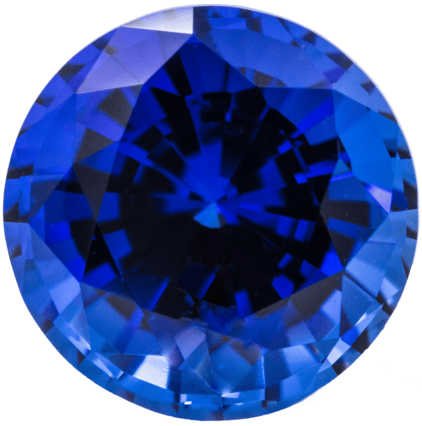
SAPPHIRE



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What is SAPPHIRE

Safe Access for Personal Patient Health Information and Records Environment (SAPPHIRE) is a research programme to evaluate the benefits and limitations of new technologies for improving use of existing patient data. SAPPHIRE is not a data collection platform but a research programme aimed solely at utilising existing data in a safer and more effective way.

SAPPHIRE aims to:

- Use advanced technologies to achieve rapid clinical insights for healthcare improvement while ensuring that patient privacy is safe
- Empower patients to contribute their data with consent and co-create and evaluate research questions using their contributed data in a way which is both effective and safe

To accomplish these aims, this will be a unique collaboration between academia and industry. We are working with Patients Know Best (PKB), a leading Personal Health Record (PHR) platform which allows patients to share selected parts of their medical data with select clinicians, carers and researchers. Our other partner is MDClone (MDC), a proven platform for generating anonymised data using advanced technologies.

Why do we need SAPPHIRE

Despite the theoretical benefits of using patient data for clinical research, these benefits are often delayed, sometimes indefinitely, by data privacy concerns and associated access procedures which accompany sharing of data.

Standards for traditional methods of safely sharing data, meant to address these concerns, cannot be universally agreed or applied. This means that patient data is not being used to improve healthcare as effectively as it could.

Although SAPPHIRE abides by all established regulatory and recommended guidance for use of patient data, it also utilises advanced technologies to this more effectively leading to quicker insights and improvements for patient care.

What are the benefits of SAPPHIRE

Patients and carers will benefit from more effective use of data, faster translation of clinical insights to healthcare improvement and direct engagement in research activity.

Clinicians will benefit from an easier way of collecting and accessing insights from patient data for clinical quality improvement.

Researchers will be able to safely and instantaneously run large scale clinical research using clinical data.

Decision makers will benefit from rapid methods for utilising real-world evidence to create more robust policies.

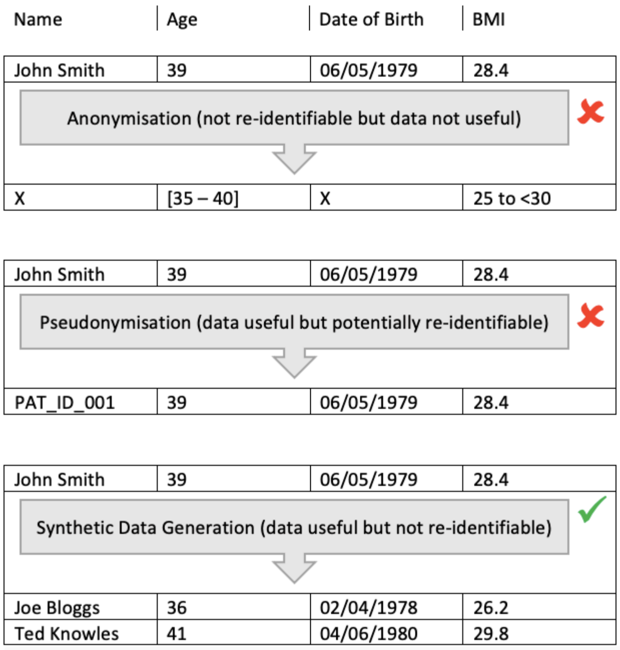
How will SAPPHIRE work

SAPPHIRE will enable *safe theory testing* and *safe theory validation* using advanced technologies. These concepts are defined below.

Safe theory testing

To enable safe theory testing, SAPPHIRE will provide synthetic data. Synthetic data is very similar to real data, but synthetic data contains no real people and is completely anonymised. Like the gem on the cover, which looks like a real SAPPHIRE but is a lab-grown synthetic gem, synthetic data is very similar to real data but is generated, based on real data, rather than naturally developed.

Unlike typical anonymisation, synthetic data retains similar features to original data which can be used to do research, although it cannot be used to make clinical decisions. In Figure 1 you can see the difference between anonymisation methods and how they produce different levels of usable data.



Name	Age	Date of Birth	BMI
John Smith	39	06/05/1979	28.4

Anonymisation (not re-identifiable but data not useful) ✗

X	[35 – 40]	X	25 to <30

John Smith	39	06/05/1979	28.4

Pseudonymisation (data useful but potentially re-identifiable) ✗

PAT_ID_001	39	06/05/1979	28.4

John Smith	39	06/05/1979	28.4

Synthetic Data Generation (data useful but not re-identifiable) ✓

Joe Bloggs	36	02/04/1978	26.2
Ted Knowles	41	04/06/1980	29.8

Figure 1: Anonymisation methods in practice

Synthetic data will enable researchers to make progress on research much more quickly and refine their insights in the process without putting patient privacy at risk. Once tested on the synthetic data, researchers can decide whether it would be beneficial to validate their tested theories using real data.

Safe Theory Validation

As synthetic data cannot be used to make clinical decisions, especially for cases of rare disease where patient numbers are small, it is important that researchers have a method to validate theories using real data.

SAPPHIRE enables this by providing an environment for allowing researchers to apply the same exact methods tested on synthetic data to real data without exposing the data to the researchers. Outputs from this environment are automatically screened to ensure that patient privacy is maintained in outputs. Researchers only have access to this final anonymised output.

How is my data protected in SAPPHIRE

Protection of patient data is paramount throughout this programme, as well as appropriate support for a patient involvement and engagement strategy.

Patient Involvement and Engagement

This document has been co-created with patients to ensure that patients approve of how SAPPHIRE operates. Furthermore, both PKB and non-PKB patients are on the SAPPHIRE advisory committee to advise on patient requirements. Regular workshops open to patients, carers, clinicians and researchers are held to co-design research, co-create public facing materials, review research questions and outputs and ensure that any on-going questions are addressed. Patients who are part of council and workshops are supported and paid for their time and travel, as per INVOLVE guidelines.

Data Protection

At no time does anyone have access to directly identifiable data other than registered PKB patients and the clinicians that treat them. All data held in PKB is encrypted and PKB employees cannot access this data. All data held in SAPPHIRE is anonymised by PKB, following existing standards, prior to transfer to SAPPHIRE. Researchers are only able to access completely anonymised data through formulated research questions. For more detail about patient privacy see the SAPPHIRE privacy notice.

SAPPHIRE does not manage actual health records or patient consent, it merely borrows data from PKB to create synthetic dataset and research outputs. Research outputs will be shared in PDF form with patients and clinicians in the PKB interface. Data derived from PKB is only held temporarily in SAPPHIRE as data can be regenerated and reused at any time without need for permanent storage in SAPPHIRE.

Patients can opt-out of SAPPHIRE at any time and their data will be removed from SAPPHIRE systems. Their PKB record will be unaffected.

Who is eligible to participate in SAPPHIRE

In its research phase SAPPHIRE is only available to patients who use PKB, a leading PHR provider. PKB was chosen as it offers functionality which is not provided by other PHR providers currently. Namely it allows patients to selectively choose what data they want to share with the SAPPHIRE research platform.

PKB holds data on patients across the UK, representative of different age, gender, ethnicity, lifestyle, urban, rural and socio-economic status. It is estimated that at least 1.4 million patients are currently eligible for SAPPHIRE. Figure 2 gives an example of the potential coverage of the PKB platform as of the writing of this material.

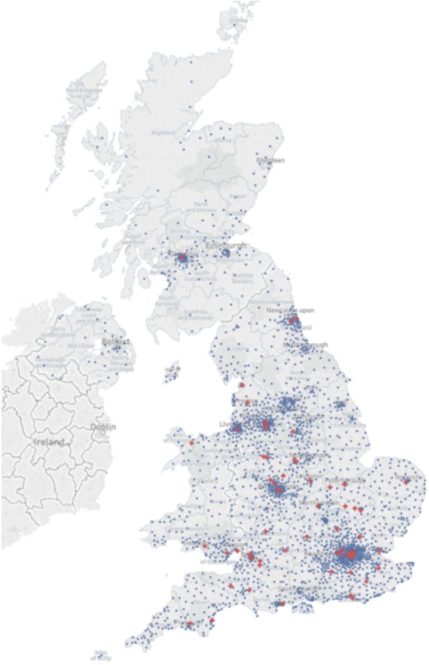


Figure 2: PKB coverage

To highlight any limitations of data provided by PKB, we will attempt to replicate a sample of applicable research questions and results in nationally representative datasets already accessible by the SAPPHIRE team.

In the long-term we would like all patients to be eligible for participation in SAPPHIRE. We will work with other personal health record providers to maintain patient consent and control.

More Information

The SAPPHIRE team can be reached by emailing sapphire@imperial.ac.uk for more information.

Please see the privacy notice for a full legal overview of your rights. If you want to find out more about how we use your information, you can also contact Imperial College London's Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner's Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (Imperial) first before involving the regulator.

[1] https://fireandbrilliance.com/products/round-chatham-lab-grown-blue-sapphire-gems?variant=3132843556892